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| EXAMINER |
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MENDOZA, MICHAEL G

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| ART UNIT | PAPER NUMBER |
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3734

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12/08/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. 10/597,299 | Applicant(s) MONSTADT, HERMANN | |
| | Examiner MICHAEL G. MENDOZA | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see page 6 of the arguments, filed 9/21/2010, with respect to claims 3-5 have been fully considered and are persuasive. The 35 USC 112 rejection of claims 3 has been withdrawn.
2. Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new ground(s) of rejection. The applicant has amended the independent claim to include new limitations requiring new consideration.
3. Claims 1-23 are pending.
4. Claims 24 has been cancelled.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Regarding claims 1, 3-7, 9, and 13-16, the word "means" is preceded by the word(s) "securing" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-17 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bashiri et al. 6165178 in view of Aganon et al. 7166122.

10. Bashiri et al. teaches a device comprising an insertion aid (102), at least one occlusion helix (120), the at least one occlusion helix comprising a longitudinally-oriented lumen (see figs.), a securing means extending through the lumen; at least one electrolytically corrodible severance element (112), with at least one stabilization helix (127) being arranged between severance element (112) and occlusion helix (127), characterized in that the stabilization helix (127) being connected with the occlusion helix (120) by an electrically isolating adhesion layer (125) such that the occlusion helix (120) becomes isolated from voltage when an electrical voltage is applied to the severance element (112). It should be noted that Bashiri et al. fail to specifically teach wherein the securing means extends through the lumen to a distal front section of the at least one occlusion helix.

11. Aganon et al. teaches a device with a common securing means extending through a lumen to a distal front section of the at least one occlusion helix (fig. 1) for preventing unwanted stretch though the device during positioning. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was

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made to modify the device of Bashiri et al. in view of Aganon et al. to include securing means extending through a lumen to a distal front section of the at least one occlusion helix to prevent stretching through the entire device for proper positioning.

12. Aganon et al. also teaches the limitation of wherein the at least one securing means is connected to the distal front section of the at least one occlusion helix with a distally electrically isolating distal adhesion layer (the distal cap 107 is made of thermoplastics).

13. Bashiri/Aganon teaches the device according to claim 1, wherein the stabilization helix (127) comprises an electrically isolating coating (col. 6, lines 8-16); and wherein a securing means (129) extends through the lumen of the occlusion helix (120); wherein the securing means consists of a material having shape-memory properties (nitinol, col. 8, lines 56-col. 9 line 45, Aganon); wherein the securing means (129) is configured to transform and assume a previously impressed structure configuration when placed into the blood vessel or body cavity (definition of shape-memory); wherein the securing means (129) consists of Nitinol (col. 9, lines 14-25); wherein at least one securing means extends from the stabilization helix to the distal front section of the at least one occlusion helix; wherein the at least one securing means is connected with the distal front section of the at least one occlusion helix via an electrically isolation distal adhesion layer configured to isolate the occlusion helix from an electrical voltage applied to the severance element; wherein the securing means is provided with an electrically isolating coating (col. 15, lines 42-46 Aganon); wherein the at least one occlusion helix comprises an inner side with an electrically isolating coating (col. 8, lines

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4-12, Aganon); wherein the at least one occlusion helix is provided with a plurality of spaced electrolytically corrodible severance elements (see figs., Aganon); further comprising a plurality of spaced occlusion helices with an electrolytically corrodible severance element arranged between each of the individual spaced occlusion helices (fig. 6, 312(1)-312(3), Aganon); further comprising a securing means arranged in a segment of the at least one occlusion helix located between the plurality of spaced electrolytically corrodible severance elements (fig. 6, 308(1)-308(4), Aganon); wherein at least one of the securing means extend from one stabilization helix connected by a severance element to the next distally located stabilization helix (fig. 6, Aganon); wherein at least one of the securing means extends from one severance element to the next distally located severance element (fig. 6 Aganon); wherein the plurality of spaced electrolytically corrodible severance elements are connected with each other so as to be electrically conductive via the securing means extending through the lumen of the at least one occlusion helix (a conductive filler can be used conductive connect the securing means); wherein the electrically isolating adhesion layer comprises an acrylate adhesive (polyvinylchloride, col. 15, lines 42-46, Aganon); wherein the occlusion helices comprise the material selected from the group consisting of platinum, a platinum alloy, and a platinum-iridium alloy (col. 7, lines 61-65, Aganon); wherein the insertion aid is a guide wire (col. 2, lines 14-19); and wherein the device is a micro-catheter (col. 2, lines 35-38).

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14. Claim 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bashiri et al. in view of Aganon et al. as applied to claim 1 above, and further in view of Monstdt et al. 7323000.

15. Bashiri/Aganon teaches the device according to claim 1. It should be noted that Bashiri/Aganon fails to teach wherein the at least one electrolytically corrodible severance element comprises a steel alloy material. Both Bashiri and Aganon teach a metal link the is dissolved through electrolysis.

16. Monstdt et al. teaches a common link using metals including a steel alloy material (col. 4, lines 59-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Bashiri/Aganon in view of Monstdt et al. to make the link with the metal described including steel alloy material as a matter of mere design choice since the are all alternatives for each other.

17. Bashiri/Aganon/Monstdt teaches the device according to claim 1 wherein the at least one electrolytically corrodible severance element is pre-corroded (col. 5, lines 63-66).

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./

Examiner, Art Unit 3734

/EDUARDO C. ROBERT/

Supervisory Patent Examiner, Art Unit 3733